IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS TEXARKANA DIVISION

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BETTY ALSTON, ARTHUR ALTSHER, GENE ANDERSON, LINDY ANDERSON, MICHAEL ANDERSON, ALMA ROSA APONTE, MARY ARNOLD, ANTHONY AUGUSTA, DIANE BARNES. INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF MICHAEL BARNES, DECEASED, ERNIE BEENE, WILLIE BOWIE, DANA BRADFORD, STEPHEN **BRAME, GARY BRAULT, MARY** BRAWN, ALVIN BRIDGERS, BYRTLE BROWN, MIKE BROWN, NANCY BROWN, ROBERT BRUETT, INDIVIDUALLY AND AS REPRESENTATIVE OF THE ESTATE OF STEPHEN FELTON, DECEASED, NATHANIEL BRYANT, DAVID BUNCE, ALEASE BYRD, SHEREE CANNON, SANDRA CAPRARO. TABON CARROLL, ROBERT CATLIN, LINDA CAWLEY. RAYMOND CHAPPLE, TONY CHAVEZ, JEMAL CHERRY, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF EVELYN DRUMGOOLE, DECEASED, LLYRIS CHIZER, VESTA CLAY, JUNIOR COBB, ERNEST COLMON, EVELYN COLON, CYNTHIA COMBS, RONALD CONNAUGHTY, BOBBIE COOKS, CATHY COOPER, RICKY CUE, HUNTER DASKER, **CATHIEANN DAVIS, ROSEMARIE** DAVIS, MICHAEL DOMINGUEZ, DOROTHY DOUGLAS, PEARLINE **DUBOSE, JEFF DURAND, SHARON DURHAM, APRIL EARLY, BEVERLY** EASON, CALLIE EHRHARDT, BRUCE ELEY, ROBERT ESTOCK. PATRICK FIEDLER, RUSS FISH,

Civil Action No. 506CV

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Jury Requested

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FAIRANN FISK, LINDA FLORES, JESSE FRANKLIN, BARBARA FRAZIER, HELEN FRIERSON. GLENN GAINES, BEATRIZ GARCIA, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF STEVE GONZALEZ, DECEASED, GILBERT GARCIA, LUPE GARCIA, MARY GARDNER, SCOTT GARRISON, BETTY GATHERS. SUSANNE GIBBS, JOANN GILBERT, DEBRA GILDART, JESSE GLOVER, ISIAH GOODEN, CLARENCE GRAHAM, MAMIE GREEN, MELVIN GREEN, GWENDOLYN GREER, DANIEL GRIFFIN, CHARLES HALL, LISA HALL, MARK HANSEN, JOY HARRINGTON, LANEETA HARRINGTON, DONALD HARRIS, DOROTHY HARRISON, SHARON HARRISON, ADELE HENDERSON, DONNA HENDERSON, DAVID HILL, DAVID HOADLEY, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF LEANN HOADLEY, DECEASED, RICHARD L HOPKINS, DONALD § HORNYAK, DONALD HOUSE, JESSE § HOWARD, JANET HUBBARD, CAROLYN HUGGINS, JOHN HURT, LAWRENCE INGRAM, FAUN § JACKSON, JUDY JACKSON, GLORIA JACOBS, DONALD JOHNSON, ERNEST JOHNSON, MICHAEL JOHNSON, QUEEN JOHNSON, MARY JANE JONES, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF LISA WELCH, DECEASED, HARRIET JONES, JERRY KANGAS, THURMAN KEARNEY, BOB KEENEY, CORA KELLY, NINA KING, LINDA KIRTZ, SHEILA KOCH, CHRISTINE KROMMINGA, PAULINE LACOMBE, PATRICIA LADD, DANIEL LAMBERT, BEULAH

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LAWSON, JENNIFER LEARY, RITA LENEAU, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF MARY FORD. **DECEASED, GARY LEWIS, GREGORY LEWIS, LINDA LEWIS,** SIMONNE LIBERTE, KENNETH LOLLIS, ALAN LONDE, STEVE LOPEZ, JOSEPH LUI, JOSEPH LUSSIER. DENNIS LUTHER. FRANKIE MADISON, RONNIE MARQUEZ, GRACE MATSON, PATRICIA MATSON, MICHAEL **MATTHEWS, STACY MAY, MELISSA** MCCARTHY, MICHELLE MCCASKILL, TAJHA MCCLOUD, JOSEPH MCCULLOUGH, ANNIS MCKINNEY, CAROLYN MCKNIGHT, BENNY MERRITT, JANICE MILLER, REINA MONTOYA, CELESTINE MOORE, GLENN MOORE, RITA MOORE, TERRENCE MOORE, WILLIAM MOORE, MICHAEL MOORE, RAYMOND MOYNIHAN, **NELL MUSTARD, ALMA** NEWHOUSE, CURTIS O' HAIRE, LILIANA ORTIZ, MISTY OVALLE, MICHAEL PACHECO, KAREN PAGE, **DWIGHT PATTERSON, ARTHUR** PEREZ, JOSEPH PEREZ, WILLIAM 88888 PERILLO, ANNIE PETERKIN, VALORIE PETERS, BRIAN PETERSON, PATRICIA PEZEWSKI, MARY PIRTTLE, MATTHEW § PITTMAN, JOANN PLEASANT, § YORK POLK, CAROLYN PRIDGEON. INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE § OF ARTHUR HALL, DECEASED. § EMANUAL REDD, ROSEMARY § 8888 RIDDLE, GWENDOLYNN ROBINSON, WILLIE ROBINSON, JETTA ROBISON, ERIN ROGERS, PATRICIA ROHRIG, ROBERT ROSALES, TOMMIE ROSNER, BETTY ROSS, FLOYD RUBLE,

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DENISE RUSH, JOSEPHINE SANDERS, MARYLIN SANDERS, **OLIVER SANDERVILLE, ALICIA** SAVAGE, SANDRA SCADDEN, SHERANN SCOTT, BRENDA SCOTTBERG, JUANITA SHARPE, MILDRED SHAW, SHIRLEY SHIVER, SHARON SIMMONS, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF ETHEL SIMMONS, DECEASED, LLOYD SIMMONS, VIOLA SIMMONS, CYNTHIA SIMS, QUINCY SIMS, GERALDINE SIPP, ANITA SMITH, DONZELLA SMITH, EDWARD SMITH, KAREN SMITH, NEAL SMITH, ROSA SMITH, TIMOTHY SMITH, DEBORAH SMITH-WEBB, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF CLARENCE WEBB, DECEASED, PATRICIA SMOLICK, COHEN SPRINKLE, JIMMIE STEPHENS, JUANITA STEPHENS, LARRY STROMAN, JOHN STUMP, ROSEMARIE SUAZO, BOBBY SUTTON, SHEILA TART, GAYLEN TAYLOR, ROSETTA TERRY, RONALD TOLLE, MICHAEL § TORRENCE, WILLIE TURNER, VECENIA UPSHAW, JOSE VEGA, § § § § **CARLOS VELEZ, STEPHEN** WADDELL, ARTHUR WALKER, JOSEPH WEAVER, BARBARA WEBB, JASON WEBBER, DAVID 88888 WILKERSON, KATHLYN WILKERSON, GREGORY WILLIAMS, ROBERT WILLIAMS, ROBERT WILLIAMS, MAXINE WILLIAMSTON, BONNIE WISE, **TIMOTHY WISE, ROBERT** WOGGERMAN, DAVID WOODS, PRINCINA WRIGHT, JANNETTA **§** § § YAX, BARBARA YEAKLE, THERESA ZAGRANIS, Plaintiffs,

vs. \$

ELI LILLY AND COMPANY, \$

Defendant. \$

PLAINTIFFS' ORIGINAL COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

COME Now Plaintiffs (hereinafter collectively referred to as "Plaintiffs"), complaining of ELI LILLY AND COMPANY, and for cause of action would respectfully show unto the Court and the Jury the following:

I. Introduction

1. This is a civil action brought on behalf of Plaintiffs regarding damages which occurred as a result of Plaintiffs' ingestion of the prescription drug, Zyprexa, also known as Olanzapine (hereinafter referred to as "Zyprexa"). Zyprexa was manufactured, marketed, distributed and sold to Plaintiffs by Defendant and/or its representatives.

II. PARTIES

A. PLAINTIFFS

2. Plaintiffs are individuals, who currently reside in various U.S. States, as indicated below:

LIST OF PLAINTIFFS (1-245)

	First Name	Last Name	State of Residence
1	Betty	Alston	SC
2	Arthur	Altsher	CA
3	Gene	Anderson	WI
4	Lindy	Anderson	SC
5	Michael	Anderson	CA
6	Alma Rosa	Aponte	MA

7	Mary	Arnold	SC
8	Anthony	Augusta	MA
9	Diane	Barnes, Individually and as Personal Representative of the Estate of Michael Barnes, Deceased	ОН
10	Ernie	Beene	IN
11	Willie	Bowie	WI
12	Dana	Bradford	OH
13	Stephen	Brame	CA
14	Gary	Brault	MA
15	Mary	Brawn	IA
16	Alvin	Bridgers	SC
17	Byrtle	Brown	SC
18	Mike	Brown	OH
19	Nancy	Brown	OK
20	Robert	Bruett, Individually and as Representative of the Estate of Stephen Felton, Deceased	IA
21	Nathaniel	Bryant	IL
22	David	Bunce	IA
23	Alease	Byrd	SC
24	Sheree	Cannon	WI
25	Sandra	Capraro	IL
26	Tabon	Carroll	SC
27	Robert	Catlin	ME
_ 28	Linda	Cawley	MA
29	Raymond	Chapple	WI
30	Tony	Chavez	NM
31	Jemal	Cherry, Individually and as Personal Representative of Evelyn Drumgoole, Deceased	MD
32	Llyris	Chizer	CA
33	Vesta	Clay	NH
34	Junior	Cobb	AR
35	Ernest	Colmon	ОН
36	Evelyn	Colon	PA
37	Cynthia	Combs	ОН
38	Ronald	Connaughty	МО
39	Bobbie	Cooks	WI
40	Cathy	Cooper	AZ
41	Ricky	Cue	SC

42	Hunter	Dasker	CA
43	Cathieann	Davis	CA
44	Rosemarie	Davis	WI
45	Michael	Dominguez	CA
46	Dorothy	Douglas	WI
47	Pearline	DuBose	OH
48	Jeff	Durand	MA
49	Sharon	Durham	WV
50	April	Early	WV
51	Beverly	Eason	GA
52	Callie	Ehrhardt	SC
53	Bruce	Eley	ОН
54	Robert	Estock	IL
55	Patrick	Fiedler	IL
56	Russ	Fish	NM
57	Fairann	Fisk	NV
58	Linda	Flores	NV
59	Jesse	Franklin	m IL
60	Barbara	Frazier	CA
61	Helen	Frierson	SC
62	Glenn	Gaines	ОН
63	Beatriz	Garcia, Individually and as Personal Representative of the Estate of Steve Gonzalez, Deceased	CA
64	Gilbert	Garcia	NM
65	Lupe	Garcia	CA
66	Mary	Gardner	GA
67	Scott	Garrison	IL
68	Betty	Gathers	SC
69	Susanne	Gibbs	IN
70	Joann	Gilbert	NM
71	Debra	Gildart	WI
72	Jesse	Glover	SC
73	Isiah	Gooden	SC
74	Clarence	Graham	SC
75	Mamie	Green	SC
76	Melvin	Green	SC
77	Gwendolyn	Greer	ОН
78	Daniel	Griffin	ОН
79	Charles	Hall	SC
80	Lisa	Hall	ОН

81	Mark	Hansen	WI
82	Joy	Harrington	DE
83	Laneeta	Harrington	OH
84	Donald	Harris	OK
85	Dorothy	Harrison	CA
86	Sharon	Harrison	WV
-	Adele	Henderson	GA
87		Henderson	OH
88	Donna	Henderson	IA
90	David David	Hoadley, Individually and as	IA
90	David	Personal Representative of the Estate of Leann Hoadley, Deceased	17.1
91	Richard L	Hopkins	OH
92	Donald	Hornyak	ОН
93	Donald	House	WI
94	Jesse	Howard	CA
95	Janet	Hubbard	ΙA
96	Carolyn	Huggins	GA
97	John	Hurt	OH
98	Lawrence	Ingram	SC
99	Faun	Jackson	MO
100	Judy	Jackson	CA
101	Gloria	Jacobs	NC
102	Donald	Johnson	WV
103	Ernest	Johnson	WI
104	Michael	Johnson	OH
105	Queen	Johnson	SC
106	Mary Jane	Jones, Individually and as Personal Representative of the Estate of Lisa Welch, Deceased	WV
107	Harriet	Jones	SC
108	Jerry	Kangas	CA
109	Thurman	Kearney	SC
110	Bob	Keeney	MO
111	Cora	Kelly	MA
112	Nina	King	WI
113	Linda	Kirtz	IN
114	Sheila	Koch	MO
115	Christine	Kromminga	IA
116	Pauline	Lacombe	MA
117	Patricia	Ladd	SC

118	Daniel	Lambert	WI
119	Beulah	Lawson	WV
120	Jennifer	Leary	MA
121	Rita	Leneau, Individually and as Personal Representative of the Estate of Mary Ford, Deceased	SC
122	Gary	Lewis	CA
123	Gregory	Lewis	CA
124	Linda	Lewis	NY
125	Simonne	Liberte	MA
126	Kenneth	Lollis	SC
127	Alan	Londe	MO
128	Steve	Lopez	IL
129	Joseph	Lui	CA
130	Joseph	Lussier	MA
131	Dennis	Luther	WI
132	Frankie	Madison	SC
133	Ronnie	Marquez	NM
134	Grace	Matson	WI
135	Patricia	Matson	MO
136	Michael	Matthews	CA
137	Stacy	May	MO
138	Melissa	McCarthy	OH
139	Michelle	McCaskill	SC
140	Tajha	McCloud	GA
141	Joseph	Mccullough	NC
142	Annis	Mckinney	WV
143	Carolyn	McKnight	GA
144	Benny	Merritt	GA
145	Janice	Miller	IL
146	Reina	Montoya	NM
147	Celestine	Moore	OH
148	Glenn	Moore	CA
149	Rita	Moore	MD
150	Terrence	Moore	NC
151	William	Moore	NM
152	Michael	Moore	IL
153	Raymond	Moynihan	DE
154	Nell	Mustard	OH
155	Alma	Newhouse	WV
156	Curtis	O' Haire	IL

157	Liliana	Ortiz	MA
158	Misty	Ovalle	CA
159	Michael	Pacheco	CA
160	Karen	Page	IL
161	Dwight	Patterson	WI
162	Arthur	Perez	NM
163	Joseph	Perez	CA
164	William	Perillo	PA
165	Annie	Peterkin	SC
166	Valorie	Peters	FL
167	Brian	Peterson	IA
168	Patricia	Pezewski	WI
169	Mary	Pirttle	IL
170	Matthew	Pittman	OH
171	Joann	Pleasant	MA
172	York	Polk	WI
173	Carolyn	Pridgeon, Individually and as	NC
		Personal Representative of the	
		Estate of Arthur Hall, Deceased	
174	Emanual	Redd	ОН
175	Rosemary	Riddle	NC
176	Gwendolynn	Robinson	AR
177	Willie	Robinson	CA
178	Jetta	Robison	МО
179	Erin	Rogers	GA
180	Patricia	Rohrig	OH
181	Robert	Rosales	CA
182	Tommie	Rosner	AZ
183	Betty	Ross	OH
184	Floyd	Ruble	IA
185	Denise	Rush	SC
186	Josephine	Sanders	SC
187	Marylin	Sanders	SC
188	Oliver	Sanderville	NM
189	Alicia	Savage	OH
190	Sandra	Scadden	<u>IA</u>
191	Sherann	Scott	NV
192	Brenda	Scottberg	<u>IL</u>
193	Juanita	Sharpe	NC
194	Mildred	Shaw	NC
195	Shirley	Shiver	SC

196	Sharon	Simmons, Individually and as Personal Representative of the Estate of Ethel Simmons, Deceased	GA
197	Lloyd	Simmons	SC
198	Viola	Simmons	SC
199	Cynthia	Sims	MA
200	Quincy	Sims	CA
201	Geraldine	Sipp	GA
202	Anita	Smith	NC
203	Donzella	Smith	OH
204	Edward	Smith	NC
205	Karen	Smith	SC
206	Neal	Smith	ОН
207	Rosa	Smith	NC
208	Timothy	Smith	WI
209	Deborah	Smith-Webb, Individually and as Personal Representative of the Estate of Clarence Webb, Deceased	ОН
210	Patricia	Smolick	FL
211	Cohen	Sprinkle	NC
212	Jimmie	Stephens	IA
213	Juanita	Stephens	MO
214	Larry	Stroman	SC
215	John	Stump	OH
216	Rosemarie	Suazo	NM
217	Bobby	Sutton	OK
218	Sheila	Tart	SC
219	Gaylen	Taylor	MO
220	Rosetta	Terry	GA
221	Ronald	Tolle	OH
222	Michael	Torrence	MA
223	Willie	Turner	GA
224	Vecenia	Upshaw	OH
225	Jose	Vega	CA
226	Carlos	Velez	CA
227	Stephen	Waddell	CA
228	Arthur	Walker	SC
229	Joseph	Weaver	IL
230	Barbara	Webb	SC
231	Jason	Webber	SC
232	David	Wilkerson	MO

233	Kathlyn	Wilkerson	OH
234	Gregory	Williams	CA
235	Robert	Williams	MA
236	Robert	Williams	NM
237	Maxine	Williamston	OH
238	Bonnie	Wise	IA
239	Timothy	Wise	SC
240	Robert	Woggerman	OH
241	David	Woods	WV
242	Princina	Wright	SC
243	Jannetta	Yax	CA
244	Barbara	Yeakle	MD
245	Theresa	Zagranis	RI

B. DEFENDANT

3. Defendant **ELI LILLY AND COMPANY**, "Lilly" is a company organized and existing under the laws of the State of Indiana with its principal place of business in Indiana. At all material times herein, Defendant advertised, marketed, promoted, sold and/or distributed Zyprexa in the State of Texas, and more specifically in the Eastern District of Texas. Defendant may be served with process of this Court upon its registered agent for service of process in Texas, to wit: National Registered Agents, Inc., 1614 Sidney Baker Street, Kerrville, TX 78028.

III. JURISDICTION & VENUE

4. The Court has jurisdiction over this lawsuit under 28 U.S.C. §1332(a)(1) because the Plaintiffs and the Defendant are citizens of different states and the amount in controversy exceeds \$75,000, excluding interest and costs. This Federal Court sitting in diversity may exercise personal jurisdiction over Defendant under the Texas long-arm statute which is consistent with the United States Constitution. Venue is proper in this Court under 28 U.S.C. §1391(c) in that the Defendant resides, transacts business, and has placed its products into the stream of commerce for sale in the Eastern District of Texas. The Judicial Panel on Multidistrict

Litigation has assigned MDL-1596; *In re Zyprexa Liability Litigation* to Sr. J. Jack B. Weinstein in the Eastern District of New York.

IV. FACTS

- 5. At all times relevant herein, Defendant was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing pharmaceuticals, including Zyprexa, for use by the mainstream public, including Plaintiffs.
- 6. Zyprexa is among a group of drugs known as "atypical antipsychotics" or "second generation antipsychotics," which was initially approved in September 1996 by the U.S. Food and Drug Administration (hereinafter the "FDA").
- 7. The initial indication approved by the FDA was for treatment of adults with schizophrenia, a relatively rare condition that affects less than one percent of the population of the United States.
- 8. In 2001, Defendant was able to get the FDA to approve Zyprexa for the short-term treatment of acute manic episodes associated with Bipolar I Disorder.
- 9. Despite its limited approval, and relatively small indicated target population, in eight years after its launch Zyprexa had become the third-best selling drug in the world. Zyprexa's worldwide sales in 1997, its first full year on the market were \$500 million. According to Defendant's Form 10K, 2004 worldwide Zyprexa sales exceeded \$4.4 billion, which made Zyprexa Defendant's top selling drug by over \$3.2 billion.
- 10. Critical to this blockbuster success was Defendant's aggressive marketing of Zyprexa, which consisted chiefly of overstating the drug's uses (including massive off-label promotion) while understating and outright concealing its life-threatening side effects.

- 11. Medical literature dating back as far as the 1950s, and Defendant's own pre-clinical studies regarding Zyprexa, demonstrated that Zyprexa had the potential to cause diabetes, diabetes-related injuries (e.g. severe weight gain, hyperglycemia, diabetic ketoacidosis), pancreatitis, cardiovascular complications, and other severe adverse effects. Despite this knowledge, Defendant never attempted to provide an adequate warning label including these risks in either the original label, or in the 17 different label revisions since then, until it was finally forced to do so by the FDA.
- 12. Almost immediately after Zyprexa's launch, there began to be large numbers of adverse event reports filed with the FDA's Medwatch database involving diabetes-related illnesses associated with Zyprexa, all of which were reported to the FDA and known to Defendant.
- 13. In 2002, nearly a year and a half before attempting to warn of the risk of diabetes in the United States, Defendant changed its labeling in the United Kingdom and Japan to include warnings regarding the association between Zyprexa and diabetes-related injuries.
- 14. On September 11, 2003, the FDA informed all manufacturers of atypical antipsychotic drugs, including Defendant, that due to an increasing prevalence of diabetes-related illnesses associated with this class of drugs, that all labeling must bear the following language in the Warnings section:

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiologic

studies suggest an increased risk of treatment emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical monitored symptoms antipsychotics should be for hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

- 15. Despite the FDA mandate, however, Defendant waited an additional six (6) months, until March 1, 2004 to send out a "Dear Doctor Letter" advising of the new warnings, which did not appear in the Physicians' Desk Reference until the 2005 edition.
- 16. Rather than risk losing the massive revenue generated by the cash cow that Zyprexa had become, Defendant immediately employed its marketing and sales force to downplay the new warnings as a mere regulatory precaution and to get out the spin that it was actually the other atypical antipsychotics that were to blame for the whole class of drugs getting relabeled.
- 17. The statements, representations and promotional schemes employed by Defendant were known by Defendant to be false, deceptive, incomplete, misleading and untrue. Nevertheless, Defendant had economic interests at heart when it proceeded with its schemes in conscious disregard for the health and safety of consumers such as Plaintiff.
- 18. In March 2004, the U.S. Attorney for the Eastern District of Pennsylvania commenced an investigation in Defendant's marketing practices concerning Zyprexa.

19. As a result of Defendant's callous disregard for human safety in the name of profits, Plaintiffs have suffered the injuries, damages, and losses complained of herein.

V. DISCOVERY RULE & FRAUDULENT CONCEALMENT

- 20. The nature of Plaintiffs' injuries and their relationship to Zyprexa use were inherently undiscoverable; and, consequently, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew or through the exercise of reasonable care and diligence should have known of the existence of their claims against Defendant. Plaintiffs did not discover, and through the exercise of reasonable care and due diligence, could not have discovered, their injuries earlier.
- 21. Further, Plaintiffs did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendant's tortious conduct. Under appropriate application of the "discovery rule," Plaintiffs' suit was filed well within the applicable statutory limitations period.
- 22. Defendant affirmatively and intentionally lulled, induced, and otherwise prevented Plaintiffs from discovering the existence of their various causes of action against Defendant through its fraudulent acts, omissions, concealments, and suppression of the dangers associated with its drug and other information necessary to put Plaintiffs on notice. Plaintiffs have therefore been kept in ignorance of vital information essential to the pursuit of their claims, without any fault or lack of diligence on their part. Plaintiffs could not reasonably have discovered the fraudulent nature of Defendant's conduct. Accordingly, Defendant is estopped from relying on any statute of limitations to defeat any of Plaintiffs' claims.

VI. CAUSES OF ACTION

A. STRICT PRODUCTS LIABILITY

23. Defendant is liable as the manufacturer, distributor and/or seller of Zyprexa because Zyprexa, when sold, was in a defective and unreasonably dangerous condition. Defendant owed a strict duty to Plaintiffs not to harm Plaintiffs through the use of its drug.

1. DESIGN DEFECT

- 24. Zyprexa was defective in design and/or formulation in that, when it left the hands of Defendant and/or its representatives, the foreseeable risks of serious harm posed by the drug outweighed its alleged benefits. The foreseeable risks of serious harm were so great that Plaintiffs, and the general public, having known of such foreseeable risks and alleged benefits, would not have ingested Zyprexa.
- 25. Zyprexa was placed into the stream of commerce by Defendant, acting through authorized agents, servants, employees and/or representatives. Plaintiffs were prescribed Zyprexa by Plaintiffs' physicians and used the drugs in a manner reasonably foreseeable by Defendant.
- 26. The Zyprexa ingested by Plaintiffs was expected to and did reach Plaintiffs without substantial change in its condition as tested, manufactured, designed, labeled, packaged, marketed and distributed. As a result of their use of Zyprexa, Plaintiffs suffered severe, permanent and disabling injuries and related damages.

2. Marketing Defect-Inadequate and Improper Warnings

27. Zyprexa was marketed to physicians to be prescribed to their patients and was marketed and advertised directly to the consuming public. Zyprexa, as manufactured and supplied to healthcare professionals and the general public, was unaccompanied by proper

warnings regarding the serious risks of ingesting the drug. The information provided to consumers did not reflect Defendant's knowledge that Zyprexa was not safe and effective as indicated in its aggressive marketing campaign, nor were consumers made aware that ingesting the drug could result in serious injury, pain and discomfort and/or death. Additionally, Defendant committed overt acts and issued doublespeak in order to downplay the truth which began to surface. This information began to emerge in the form of adverse event reports, medical studies, and the 2003 FDA labeling change. Any attempts by Defendant to satisfy its duty to warn were compromised by the backdrop of Defendant's actions. Full and proper warnings that accurately and fully reflected the risks of serious injury and/or sudden death due to the ingestion of Zyprexa should have been disclosed by Defendant.

- 28. Plaintiffs were prescribed Zyprexa by physicians who utilized the drug in a manner reasonably foreseeable by Defendant. Zyprexa was expected to and did reach Plaintiffs without substantial change in its condition as tested, manufactured, designed, labeled, packaged, marketed and distributed. Plaintiffs were not aware of, and could not have reasonably discovered, the unreasonably dangerous nature of Zyprexa.
- 29. As the producing cause and legal and direct result of the failure to warn consumers of the defective condition of Zyprexa, as manufactured and/or supplied by Defendant and its representatives, Plaintiffs have suffered severe, permanent and disabling injuries and related damages.

B. Negligence

30. Defendant owed Plaintiffs legal duties in connection with putting Zyprexa into the marketplace to be ingested by potential patients such as Plaintiffs. Defendant breached its duties, proximately causing Plaintiffs' injuries. Specifically, Defendant failed to meet its duties to use

reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Zyprexa. Defendant is liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:

- a. Failure to adequately warn Plaintiffs and Plaintiffs' physicians of the respective known or reasonably foreseeable danger that Plaintiffs would suffer a serious injury or death by ingesting Zyprexa;
- b. Failure to adequately warn Plaintiffs and Plaintiffs' physicians of the known or reasonably foreseeable danger that Plaintiffs would suffer a serious injury or death by ingesting Zyprexa in unsafe doses;
- c. Failure to use reasonable care in testing and inspecting Zyprexa, so as to ascertain whether or not it was safe for the purpose for which it was designed, manufactured and sold;
- d. Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Zyprexa;
- e. Failure to use reasonable care in the process of manufacturing Zyprexa in a reasonably safe condition for the use for which it was intended;
- f. Failure to use reasonable care in the manner and method of warning Plaintiffs and Plaintiffs' physicians as to the danger and risks of using Zyprexa in unsafe doses;
- g. Failing to use reasonable care in maintaining its continuing duty to warn Plaintiffs and Plaintiffs' physicians of after acquired knowledge;
- h. Failure to use reasonable care under the circumstances in acquiring information about patient experience with actual usage of Zyprexa, observed effects of Zyprexa, monitoring and analyzing information on the quality, safety, efficacy, and all other aspects of reasonable vigilance and ongoing monitoring of a dangerous pharmaceutical (e.g. negligent pharmacovigilance); and
- i. Such further acts and/or omissions that may be proven at trial.
- 31. The above-described acts and/or omissions of Defendant were direct and proximate causes of Plaintiffs' injuries, diseases, and damages complained of herein.

C. Intentional Misrepresentation

- 32. Defendant made material representations that were false and that were either known to be false when made or were asserted recklessly without knowledge of their truth. These misrepresentations involved material facts concerning the character and quality of the drug in question, and reasonably implied to consumers that Zyprexa was safe and would not cause injury. Defendant failed to disclose material facts regarding the dangerous propensities of Zyprexa that were known to Defendants and within the knowledge of Defendant. Defendant was well aware of the lack of knowledge on behalf of consumers such as Plaintiffs, and of the incredible disparity between Defendant's and Plaintiffs' opportunity to fully appreciate and discover the dangerous character of Zyprexa. By failing to disclose the knowledge known and appreciated by Defendant, Defendant intended to induce Plaintiffs and their physicians into continuing to prescribe, purchase and use Zyprexa without worry. Without such knowledge and the benefit and right of informed choice regarding the dangers known to Defendant, Plaintiffs' suffered the injuries, diseases, and damages complained of herein.
- 33. Defendant had in its possession adverse drug event reports, drug studies, and other documentation about Zyprexa, and yet made the following misrepresentations:
 - a. Misrepresentations regarding the respective frequency of Zyprexa-related adverse event reports or occurrences in the drug's label, package insert or PDR label;
 - b. Misrepresentations as to the respective existence, occurrence and frequency of occurrences, severity and extent of the overall risks of Zyprexa;
 - c. Misrepresentations as to the respective efficacy of Zyprexa for both FDA approved and non-approved indications;
 - d. Misrepresentations as to the respective number of adverse events and deaths reported with the use of Zyprexa;
 - e. Misrepresentations regarding the respective nature, seriousness, and severity of adverse events reported with the use of Zyprexa.

- 34. Defendant intended that these misrepresentations be relied upon by physicians, including Plaintiffs' physicians, healthcare providers and consumers. Plaintiffs did rely upon the misrepresentations that caused Plaintiffs' injuries.
- 35. As a proximate cause and legal and direct result of Defendant's misrepresentations, Plaintiffs' suffered the injuries, diseases, and damages complained of herein.

D. NEGLIGENT MISREPRESENTATION

- 36. Defendant failed to communicate to Plaintiffs and the general public that the ingestion of Zyprexa could cause serious injuries after they became aware of such risks. Instead, Defendant represented in its marketing that Zyprexa was safe and effective.
- 37. Plaintiffs brings this cause of action against Defendant under the theory of negligent misrepresentation for the following reasons:
 - a. Defendant, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about Zyprexa, in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendant made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;
 - b. These misrepresentations were made in the course of Defendant's sales of Zyprexa to the general public, Plaintiffs and Plaintiff's physicians for the purpose of inducing continued sales and use of Zyprexa;
 - c. Defendant knew that the risk of severe physical harm existed as a result of its misrepresentations;
 - d. Plaintiffs and Plaintiffs' healthcare providers justifiably relied on Defendant's misrepresentations; and
 - e. Consequently, Plaintiffs ingested Zyprexa to Plaintiffs' detriment.
- 38. Defendant's negligent misrepresentations were direct and proximate causes of Plaintiffs' injuries, diseases, and damages complained of herein.

E. EXPRESS WARRANTY

- 39. Defendant is a merchant and/or seller of Zyprexa. Defendant sold Zyprexa to consumers, including Plaintiffs, for the ordinary purpose for which such drugs are used by consumers. Defendant made representations to Plaintiffs about the quality or characteristics of Zyprexa by affirmation of fact, promise and/or description.
- 40. The representations by Defendant became part of the basis of the bargain between Defendant and Plaintiffs. Zyprexa did not comport with the representations made by Defendant in that it was not safe for the use for which it was marketed. Plaintiffs have notified Defendant that Defendant has breached its express warranties. This breach of warranty by Defendant was a proximate cause of the injuries and monetary loss suffered by Plaintiffs.

F. IMPLIED WARRANTY

1. WARRANTY OF MERCHANTABILITY

41. Defendant is a merchant and/or seller of Zyprexa. Plaintiffs purchased Zyprexa from Defendant and used it for the ordinary purpose for which such drugs are used by consumers. At the time it was purchased by Plaintiffs, Zyprexa was not fit for the ordinary purpose for which such drugs are used because it was not manufactured, designed or marketed in a manner to accomplish its purpose safely. Defendant's breach of its implied warranty of merchantability was a direct and proximate cause of Plaintiffs' injuries, diseases, and damages complained of herein.

2. WARRANTY OF FITNESS

42. Defendant sold Zyprexa to Plaintiffs with the knowledge that Plaintiffs were purchasing said drugs for a particular purpose. Further, Defendant knew, or should have known,

that Plaintiffs were relying on Defendant's skill or judgment to select goods fit for Plaintiffs' purpose.

- 43. Defendant delivered goods that were unfit for Plaintiffs' particular purpose, and thus breached its implied warranties of fitness. Plaintiffs have notified Defendant of its breach of implied warranties of fitness.
- 44. Defendant's failure to select and sell a product which was reasonably safe for its intended use was a direct and proximate cause of Plaintiffs' injuries, diseases, and damages complained of herein.

G. UNLAWFUL MARKETING ACTIVITIES / DECEPTIVE TRADE PRACTICES

- 45. Plaintiffs are consumers who purchased Zyprexa for the purposes of treating their medical symptoms and conditions.
- 46. Defendant, as the seller and supplier of the Zyprexa taken by Plaintiffs, has knowingly and intentionally engaged in false, misleading, and deceptive acts in regards to product safety issues its aggressive marketing and sale of Zyprexa in the United States. Plaintiffs and their physicians have relied upon Defendant's false, misleading, and deceptive acts in this regard in making the decision to take and prescribe Zyprexa.
 - 47. Defendant's conduct in this regard included:
 - a. Representing that Zyprexa had certain characteristics, including being a safer antipsychotic medication without dangers of causing diabetes, diabetes-related injuries (e.g. severe weight gain, hyperglycemia, diabetic ketoacidosis), pancreatitis, cardiovascular complications, and other severe adverse effects, when in fact, Zyprexa did cause those conditions;
 - b. Representing that Zyprexa was a more effective antipsychotic, when in fact, new studies have shown that it is not;
 - c. Failing to disclose the information known to Defendant regarding the risks associated with Zyprexa with the intention of inducing Plaintiffs into using Zyprexa. Plaintiffs would not have otherwise used Zyprexa if they had been

made aware of the full knowledge known to Defendant regarding those extreme risks.

- 48. Defendant further breached express and implied warranties to Plaintiffs, which constituted producing causes of Plaintiffs' damages.
- 49. Defendant engaged in aggressive, direct-to-consumer advertising and marketing in which these misrepresentations were communicated directly to its consumers, including Plaintiffs.
- 50. Plaintiffs relied upon Defendant's false, misleading, and deceptive acts to their detriment.
- 51. Defendant's false, misleading, and deceptive acts described above were a direct producing and proximate cause of Plaintiffs' injuries, diseases, and damages complained of herein.
- 52. Plaintiffs have provided adequate written notice to Defendant under the Deceptive Trade Practices Act and hereby request that Defendant be held liable for damages recoverable under the Deceptive Trade Practices Act, including treble damages, costs, and attorney's fees.

H. CIVIL CONSPIRACY

53. Defendant knowingly agreed, contrived, combined, confederated and conspired with captured research groups, physicians, and trade groups to cause Plaintiffs' injuries, diseases, and damages by continuous downplaying of the risks associated with Zyprexa in the name of more sales. They further conspired to deprive consumers such as Plaintiffs of the opportunity of informed free choice as to whether to use Zyprexa or to expose themselves to its hidden dangers. Defendant committed the above described wrongs by willfully misrepresenting and suppressing the truth as to the risks and dangers associated with the use of Zyprexa.

- 54. In furtherance of said conspiracies, Defendant and its co-conspirators performed the following overt acts:
 - a. For years, Defendant and its co-conspirators, have been in possession of medical and scientific data, literature and test reports which clearly indicated that Zyprexa and other antipsychotic drugs could cause diabetes, diabetes-related injuries (e.g. severe weight gain, hyperglycemia, diabetic ketoacidosis), pancreatitis, cardiovascular complications, and other severe adverse effects;
 - b. Despite the medical and scientific data, literature, and test reports possessed by and available to Defendant, Defendant and its co-conspirators fraudulently, willfully, and maliciously:
 - i. Withheld, concealed, and suppressed said medical and scientific data, literature and test reports regarding the risks of diabetes, diabetes-related injuries (e.g. severe weight gain, hyperglycemia, diabetic ketoacidosis), pancreatitis, cardiovascular complications, and other severe adverse effects from the general public, Plaintiffs and Plaintiffs' physicians; and
 - ii. Caused to be released, published and disseminated medical and scientific data, literature, test reports, and marketing and promotional materials containing information and statements regarding the risks of diabetes, diabetes-related injuries (e.g. severe weight gain, hyperglycemia, diabetic ketoacidosis), pancreatitis, cardiovascular complications, and other severe adverse effects, which Defendants knew were incorrect, incomplete, outdated and misleading.
- 55. By the false and fraudulent representations, omissions and concealments set forth above, Defendant and its co-conspirators intended to induce Plaintiffs and Plaintiffs' physicians to rely upon said false and fraudulent representations, omissions and concealments, to continue to expose themselves to the dangers inherent in the use of Zyprexa.
- 56. Defendant's participation in this conspiracy was a direct and proximate cause of Plaintiffs' injuries, diseases, and damages complained of herein.

VII. DAMAGES

57. Upon trial of this case, Plaintiffs respectfully request the Court and Jury to determine the amount of loss Plaintiffs have incurred in the past and will incur in the future, not

only from a financial standpoint, but also in terms of good health and freedom from pain and worry. There are certain elements of damages provided by law that Plaintiffs are entitled to have the Jury separately consider to reasonably compensate Plaintiffs for the injuries, damages and losses incurred, as well as those to be incurred in the future. Plaintiffs have been damaged as a result of Defendants' acts and omissions complained of herein in the following particulars:

- a. Plaintiffs have incurred medical, pharmaceutical, hospital, and related expenses and may be reasonably expected to incur additional expenses in the future due to the progressive nature of their injuries;
- b. The likely progression and related life-threatening medical conditions reasonably anticipated to accompany Plaintiffs' injuries will require lifetime medical monitoring as well as domestic help and nursing care as their conditions deteriorates;
- c. Plaintiffs are subject to an extraordinarily increased likelihood of developing heart disease, strokes, high blood pressure, blindness, kidney disease, nervous system disease, amputations, dental disease, pregnancy complications, sexual dysfunction, and other diabetes related complications;
- d. Plaintiffs have endured pain and suffering, mental and emotional anguish and anxiety, and loss of the enjoyment of a normal life as a result of their injuries, and they will continue to endure the same in the future;
- e. Plaintiffs have had their future wage earning capacity impaired as a result of their injuries;
- f. Plaintiffs will likely suffer from a degree of permanent physical impairment, disability, and disfigurement as a result of their injuries as they progress in the future;
- g. Plaintiffs have been and will otherwise be prevented from participating in and enjoying the benefits of a full and complete life;
- h. Plaintiffs' spouses, where named, also seeks damages for loss of consortium; and,
- i. Plaintiffs assert a claim for prejudgment interest on all elements of damages as allowed by law.

VIII. WRONGFUL DEATH & SURVIVAL DAMAGES

- 58. In the case where Plaintiffs have suffered a wrongful death due to Defendants' acts and omissions complained of herein, Plaintiffs' heirs and representatives seek compensation for the following general and special damages including, but not limited to, damages for survival and wrongful death claims that Plaintiffs have sustained both in their individual capacity and as personal representatives of the estate:
 - a. The conscious physical pain and suffering sustained by Decedent prior to their death;
 - b. The mental anguish sustained by Decedent prior to their death;
 - c. The physical impairment suffered by Decedent prior to their death;
 - d. The disfigurement suffered by Decedent prior to their death;
 - e. Reasonable and necessary medical expenses incurred by Decedent prior to their death;
 - f. Reasonable funeral and burial expenses incurred by Decedent and their estate;
 - g. Decedent's lost earning capacity;
 - h. The loss of household services, consortium, pecuniary loss, companionship and society which Plaintiffs received from Decedent prior to their last illnesses and death;
 - i. The mental anguish suffered by Plaintiffs as a consequence of the last illnesses and death of Decedent; and,
 - j. Prejudgment interest on all elements of damages as allowed by law.

VIII. PUNITIVE DAMAGES

59. At all times relevant hereto, Defendant had actual knowledge of the defective nature of Zyprexa as set forth herein and continued to design, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the public's health and safety and in

conscious disregard of the foreseeable serious harm caused by the drug. Defendant's conduct exhibits such an entire want of care as to establish that its actions were a result of fraud, ill will, recklessness, gross negligence, malice and/or willful and intentional disregard for the safety and rights of consumers of its drugs such as Plaintiffs. Plaintiffs are therefore entitled to punitive damages.

IX. JURY DEMAND

60. Plaintiffs hereby request a trial by jury on all issues in this case.

X. PRAYER

61. WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray that upon final hearing, Plaintiffs have and recover judgment from Defendant, pursuant to the above and foregoing allegations in such amounts as found proper by a jury, which is in excess of the jurisdictional minimum of this court and as the evidence may show proper at the time of trial, together with interest thereon at the legal rate; punitive an/or exemplary damages; Plaintiffs' costs and attorneys' fees expended in prosecuting this matter; and for such other and further relief, both general and special, at law and in equity, to which Plaintiffs may be justly entitled.

Respectfully submitted,

 $\mathbf{R}\mathbf{v}$

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